K061303

MAY 25 2006

510(K) Summary of Safety and Effectiveness

As required by 807.92

1. DEVICE ESTABLISHMENT AND CONTACT PERSON

Phil Chen
CHILIN TECHNOLOGY CO. LTD
No.71, Te Lun Road, Jen Te Hsian, Tainan County 717, Taiwan, R.O.C.
Ph: +886-6-279 - 4113 ext. 533
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2. DATE SUMMARY PREPARED

14 December 2005

3. DEVICE NAME

Trade Name: Medical Display, MDM1900-1NG (1NR)
Common Name: Monochrome LCD Monitor, MonochromeDiagnostic Display, etc.
Classification Name: System, Image Processing, Radiological (CLASS II CFR 892.2050)

4. PREDICATE DEVICE

RadiForce G22 19.6" Class Monochrome LCD Monitor by EIZO NANAO CORPORATION (K041597)

5. DEVICE DESCRIPTION

Medical Display, MDM1900-1NG is a 19" monochrome LCD monitor that displays image for medical use. It provides 1.3 mega pixel (1280 x 1024/1024 x 1280) resolution with adjustable gamma gray scale for more precise diagnose use in CT, MRI, HIS and PACS. This device is not suitable for a digital mammography system.

6. DEVICE OF INTEND USE

Medical Display, MDM1900-1NG is intended to use in displaying images for review and analysis by trained medical practitioner for diagnose in CT, MRI, HIS and PACS. This device is not suitable for a digital mammography system.

7. CONCLUSION

Medical Display, MDM1900-1NG (1NR) has the same intended use as the predicate device G22, and they both share the similar characteristics except some minor differences which do not raise new questions of safety and effectiveness. The device does not contact with the patient nor does it control any life sustaining device. Therefore we concluded that it is substantially equivalent to G22 by EIZO NANAO CORPORATION (K041597).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 25 2006

Chilin Technology Co., LTD
% Mr. Marc M. Mouser
Senior Project Engineer, Program Reviewer
Underwriters Laboratories, Inc.
2600 N.W Lake Road
CAMAS WA 98607-8542

Re: K061303
Trade/Device Name: Medical Display, MDM1900-1NG (1NR)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 27, 2006
Received: May 10, 2006

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Medical Display, MDM1900-1NG (1NR)

Indications For Use: 1.3MP Medical Monochrome Reference Display, MDM1900-1NG, MDM1900-1NR is intended to use in displaying images for review and analysis by trained medical practitioner for diagnose in CT, MRI, HIS and PACS. This device is not suitable for a digital mammography system.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061303